



鲁维制药集团有限公司

Luwei Pharmaceutical Group Co.,Ltd.

Shuangfeng Industrial Park Zichuan District Zibo 255086 China

Tel: 0086 533 6220986 Fax: 0086 533 6220993

<b>CERTIFICATE OF ANALYSIS</b>			
LWPC-2C1-23-03-050		Date: APR.11,2023	
Product Name	ASCORBIC ACID	Batch No.	2230113049
Analysis Standard	BP2016/USP39/FCC10/EP8.8/E300	Quantity	22000KGS
Manufacture Date	MAR.23,2023	Expiry Date	MAR.22,2026
Analysis Contents	Analysis Standard	Analysis Results	
Characteristics	White or almost White crystals Crystalline Powder	Pass	
Identification	Positive Reaction	Positive	
Melting Point	About 190°C	190.7°C	
PH(with 2% water solution)	2.4-2.8	2.57	
PH(with 5% water solution)	2.1-2.6	2.37	
Clarity Of Solution	Clear	Clear	
Colour Of Solution	≤BY <sub>7</sub>	<BY <sub>7</sub>	
Copper	≤5ppm	<5ppm	
Heavy Metals	≤10ppm	<10ppm	
Mercury	≤0.1mg/kg	<0.1mg/kg	
Lead	≤2mg/kg	<2mg/kg	
Arsenic	≤3ppm	<3ppm	
Oxalic Acid	≤0.2%	<0.2%	
Iron	≤2ppm	<2ppm	
Cadmium(Cd)	<1mg/kg	<1mg/kg	
Related substances	Impurity C: ≤0.10%	<0.1%	
	Impurity D: ≤0.10%	<0.1%	
	Impurity E: ≤0.20%	<0.2%	
	Unspecified Impurities: ≤0.10%	Less than disregard limit	
	Total Impurities: ≤0.20%	<0.2%	
Loss of Drying	≤0.4%	0.04%	
Sulphate Ash(Residue On Ignition)	≤0.1%	0.05%	
Specific Optical Rotation	+20.5° - +21.5°	20.92°	
Residual Solvents	Pass	Pass	
Total plate count	≤100cfu/g	<100cfu/g	
E-coli	Negative	Negative	
Yeaste&molds	≤100cfu/g	<100cfu/g	
Pseudomonas	Negative	Negative	
Staphylococcus	Negative	Negative	
Salmonella	Negative	Negative	
Assay	99.0%-100.5%	99.51%	
Conclusion	<b>The Above-Mentioned Product Conforms To BP2016/USP39/FCC10/EP8.8/E300</b>		

Approved by: Jia Jinfeng

Rechecker: Chen Zi

Tester: Wang Jing